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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION**

Lashanda Cavaness, Individually and as)	Civil Action No.:
Guardian Ad Litem to L.M.R., a minor,)	
Plaintiffs,)	ORIGINAL COMPLAINT
)	
v.)	
)	
CVS Pharmacy, Inc.,)	<u>DEMAND FOR JURY TRIAL</u>
Defendant)	

PLAINTIFFS' ORIGINAL COMPLAINT AND JURY DEMAND

Plaintiff Lashanda Cavaness and Plaintiff L.M.R., a minor, pursuant to Fed. R. Civ. P. 17(c)(1)(A), by and through their undersigned counsel, bring this Complaint for damages against Defendant CVS Pharmacy, Inc. (hereinafter, “Defendant”) and in support, state the following:

1. This is an action brought on behalf of Plaintiffs, Lashanda Cavaness (hereinafter, “Plaintiff Mother”), the natural and general guardian and mother of L.M.R., a minor (hereinafter, “Plaintiff Child”), a minor, arising out of the failure of Defendant to warn about the dangers of prenatal exposure to Paracetamol, also known as Acetaminophen (hereinafter “APAP”). As a result, Plaintiffs have suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

2. Defendant entirely failed its duty to adequately warn of the hazards of prenatal

1 exposure to APAP, which was a direct and proximate cause of Plaintiffs' injuries and associated
2 damages.

3 **STATEMENT OF PARTIES**

4 3. At all material times Plaintiffs have been citizens and residents of Alameda
5 County, California, and the United States.

6 4. CVS Pharmacy, Inc. is incorporated in Delaware with its principal place of
7 business in Woonsocket, Rhode Island.

8 5. CVS Pharmacy, Inc. is involved in the research, development, testing,
9 manufacture, labeling, production, marketing, promotion, and/or sale of APAP through its over-
10 the-counter store brand, CVS Health (hereinafter, the "APAP Products").

11 6. CVS Pharmacy, Inc. is individually, and jointly and severally liable to Plaintiffs
12 for damages they suffered, arising from Defendant's design, manufacture, marketing, labeling,
13 distribution, sale, and placement of the defective APAP Products into the market, effectuated
14 directly and indirectly through its agents, servants, employees, and/or owners, all acting within
15 the course and scope of its agencies, services, employments, and/or ownership.

16 7. CVS Pharmacy, Inc. is vicariously liable for the acts and/or omissions of its
17 employees and/or agents, who were at all material times acting on behalf of CVS Pharmacy,
18 Inc. and within the scope of its employment or agency.

19 **VENUE, JURISDICTION, and DIVISIONAL ASSIGNMENT**

20 8. This Court has subject-matter jurisdiction under 28 U.S.C. § 1332(a), based on
21 complete diversity of citizenship between Plaintiffs and Defendant. *See supra* ¶¶ 3–4.

22 9. The amount in controversy exceeds \$75,000.

23 10. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because the events or
24 omissions giving rise to Plaintiffs' claims occurred in this judicial district.

25 11. Divisional Assignment: this case should be assigned to the Oakland division of
26 this district pursuant to Local Rule 3-2(c) because a substantial part of the events or omissions
27 giving rise to this action occurred in Oakland, California.

28 12. Defendant has and continues to conduct substantial business in the State of

California and in this District, distributes the APAP Products in this District, receives substantial compensation and profits from sales of the APAP Products in this District, and has made material omissions and misrepresentations and breaches of warranties in this District and caused injuries in this District to Plaintiffs, among others, so as to subject Defendant to in personam jurisdiction in this District. It was foreseeable at all times that Defendant could be haled into court in the State of California for its conduct that caused injuries to citizens of California, like Plaintiffs in this action. An exercise of in personam jurisdiction by this Court over Defendant comports fully with due process and does not offend traditional notions of fair play and substantial justice.

13. Defendant is registered to transact business in California.

FACTS COMMON TO ALL COUNTS

APAP Is Marketed as the Safe Pain Reliever

for Pregnant Women, but APAP Can Cause ASD/ADHD in Children

14. APAP is widely used by pregnant women to relieve pain or discomfort during the term of their pregnancy.

15. APAP was initially discovered in the late 1800's.

16. APAP was introduced to the US market in 1955 as the first aspirin-free pain reliever. APAP was originally marketed and sold as a product to reduce fever in children, packaged like a red fire truck with the slogan, "for little hotheads."

17. Billions of units of APAP are sold annually in North America alone.

18. APAP has long been marketed as the safest, and the *only* appropriate, over-the-counter pain relief drug on the market for pregnant women.

19. Forty to 65% of pregnant women in the United States use APAP during pregnancy.

20. Based upon information and belief, a majority of women who use APAP during pregnancy do so electively for the treatment of headaches, muscle pain, back pain, and discomfort.

21. These pregnant women electively choose to take APAP because Defendant has

1 marketed APAP as a safe pain reliever for pregnant women.

2 22. However, scientific and epidemiological research shows that prenatal exposure
3 to APAP alters fetal development significantly increasing the risks of neurodevelopmental
4 disorders, including but not limited to, autism spectrum disorder (“ASD”) and attention-
5 deficit/hyperactivity disorder (“ADHD”).

6 23. Undisturbed development of the human brain in utero is vital to the health and
7 wellness of a child’s development. The human brain is vulnerable and extremely sensitive in
8 utero. During this sensitive time-period in utero, certain chemicals have been found to cause
9 permanent brain injury at low exposure levels.

10 24. Once ingested by the mother, APAP is known to readily cross the placenta and
11 blood-brain barrier.

12 25. ASD is a serious neurological and developmental disorder that affects how
13 people interact with others, communicate, learn, and behave.

14 26. There are three functional levels of ASD, with Level 1 requiring support with
15 activities of daily living, Level 2 requiring substantial support with activities of daily living, and
16 Level 3 requiring very substantial support with activities of daily living.

17 27. Treatments for ASD include behavioral management therapy, cognitive behavior
18 therapy, joint attention therapies, medications, occupational therapy, physical therapy, social
19 skill training, and speech-language therapy. Treatment for ASD lasts a lifetime, as there is no
20 cure.

21 28. ADHD is a chronic neurodevelopmental disorder resulting in attention difficulty,
22 hyperactivity, and impulsiveness.

23 29. ADHD begins in childhood and persists through adulthood. ADHD contributes
24 to low self-esteem, troubled relationships, and difficulty with school, work, and familial
25 relationships.

26 30. Treatments for ADHD, include, but are not limited to, chronic medication usage
27 and various therapies. Treatment for ADHD lasts a lifetime, as there is no cure.

28 31. In or around 2018, the Center for Disease Control and Prevention (“CDC”)

1 found that 1 in 44 (2.3%) 8-year-old children have been diagnosed with ASD.

2 32. This represents an increase from a prior CDC finding that 1 in 68 U.S. children
3 born in 2002 have ASD, which already represented a more than a 100% increase compared with
4 children born a decade prior.

5 33. As of 2019, 8.8% of children had been diagnosed with ADHD, or roughly
6 325,000 children per year.

7 34. Parental awareness and changes in diagnoses do not account for the rapid rise in
8 these diagnoses.

9 35. Rather, neurotoxic exposures, such as prenatal APAP exposure, explain a
10 trending increase in diagnosis.

11 36. For years, the scientific community has published studies showing that prenatal
12 ingestion of APAP can cause ASD and ADHD.

13 37. For instance, since 2013, there have been six European birth cohort studies,
14 examining over 70,000 mother-child pairs, showing the association between prenatal use of
15 APAP and ASD and ADHD.

16 38. The overall body of scientific evidence has shown that prenatal use of APAP can
17 cause ASD and ADHD in the child.

18 39. During all relevant times herein, Defendant was engaged in the business of
19 manufacturing and selling the APAP Products in the United States, and the weight of the
20 scientific evidence available showed prenatal exposure to APAP significantly increases the risk
21 of neurodevelopmental disorders in children exposed to APAP prenatally, including but not
22 limited to ASD and ADHD.

23 40. At the time Plaintiff Mother was pregnant with Plaintiff Child the scientific
24 evidence regarding the risks of in utero exposure of APAP was available to Defendant, and
25 Defendant knew or should have known that prenatal use of APAP can cause ASD or ADHD.

26 41. Based on information and belief, Defendant has concealed the prenatal APAP
27 exposure-neurodevelopmental link from consumers, like Plaintiff Mother. .
28

42. Moreover, despite knowing that prenatal use of APAP can cause ASD or ADHD, Defendant continued, and continues, to market APAP Products as safe pain relievers for pregnant women, making mothers believe they are choosing a safe drug for even minor aches, pains, and headaches.

**Plaintiff Mother Took APAP Products while Pregnant,
and It Caused ASD in Plaintiff Child**

43. Plaintiff Mother began using the APAP Products when she was pregnant with her Plaintiff Child.

44. Over the course of her pregnancy, Plaintiff Mother took the APAP Products for pain relief approximately two times a day as needed for pain and discomfort.

45. Plaintiff Mother believed it was safe for her to take the APAP Products during her pregnancy.

46. Indeed, Plaintiff Mother was instructed to not take ibuprofen or aspirin while pregnant, but was informed she could take APAP freely and without risk.

47. There is no warning on the APAP Products' labels specifically addressing the risks of ASD if a mother ingests APAP while pregnant.

48. Had Plaintiff Mother known of the risk of taking APAP while pregnant, specifically that it could cause ASD in her child, she would not have taken the APAP Products.

49. Plaintiff Child was born on February 21, 2014.

50. Plaintiff Mother started to have concerns about Plaintiff Child's development before she started school. Specifically, Plaintiff Child would not make eye contact, ran in circles, had trouble with speech, and walked on her tiptoes.

51. Plaintiff Child was diagnosed with ASD when she was one year old.

52. Plaintiff Child requires an immense amount of assistance to complete the normal tasks of his daily life.

53. Plaintiff Child's ASD puts an incredible strain on Plaintiff Mother and their family.

54. Plaintiff's Mother fears for Plaintiff Child and experiences substantial stress and

1 anxiety due to the challenges associated with Plaintiff Child's ASD.

2 **ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS**

3 55. Due to Defendant's acts of fraudulent concealment, Defendant is estopped from
4 relying on any statutes of limitations or repose. Such acts include Defendant's intentional
5 concealment from Plaintiff Mother and the general public that APAP is defective when there is
6 prenatal exposure, while continuing to market the APAP Products with the adverse effects
7 described in this Complaint.

8 56. Given Defendant's affirmative actions of concealment by failing to disclose
9 information about the defects known to it but not the public—information over which
10 Defendant had exclusive control—and because Plaintiff Mother could not reasonably have
11 known that the APAP Products were defective, Defendant is estopped from relying on any
12 statutes of limitations that might otherwise be applicable to the claims asserted in this
13 Complaint.

14 **CLAIMS FOR RELIEF**

15 **COUNT I: STRICT LIABILITY – FAILURE TO WARN**

16 57. Plaintiffs restate, reallege, and incorporate by reference the allegations set forth
17 in the rest of this Complaint as if fully set forth herein.

18 58. At the time of Plaintiffs' injuries, the APAP Products were defective and
19 unreasonably dangerous to foreseeable consumers using the APAP Products in a foreseeable
20 manner during pregnancy, including Plaintiff Mother, because they lacked an adequate warning.

21 59. At all relevant times, Defendant engaged in the business of testing, developing,
22 designing, manufacturing, marketing, labeling, selling, distributing, and promoting the APAP
23 Products, which were defective and unreasonably dangerous to consumers, including Plaintiff
24 Mother, because they did not contain adequate warnings or instructions concerning the
25 dangerous characteristics of ingesting APAP during pregnancy. These actions were under the
26 ultimate control and supervision of Defendant. At all relevant times, Defendant registered,
27 researched, manufactured, distributed, marketed, labeled, promoted, and sold the APAP
28 Products within this District and aimed the marketing at the ultimate consumer. Defendant was

1 at all relevant times involved in the retail and promotion of the APAP Products marketed and
2 sold in this District.

3 60. Defendant had a duty to warn of the risks associated with the use of the APAP
4 products during pregnancy.

5 61. The APAP Products ingested by Plaintiff Mother during pregnancy were in the
6 same or substantially similar condition as they were when they left possession of Defendant.

7 62. Defendant expected and intended the APAP Products to reach users such as
8 Plaintiff Mother in the condition in which the APAP Products were sold.

9 63. Plaintiff Mother did not materially alter the APAP Products prior to ingestion.

10 64. Plaintiff Mother ingested the APAP Products during pregnancy as indicated on
11 the APAP Products' labels.

12 65. Plaintiff Mother was unaware of the defects and dangers of the APAP Products
13 during pregnancy and was specifically unaware that prenatal exposure increases the risk of brain
14 and behavioral development of children in utero.

15 66. The labels on the APAP Products to consumers lack any warning specific to
16 pregnant women. The information that Defendant did provide or communicate to consumers
17 failed to contain relevant warnings, hazards, and precautions that would have enabled
18 consumers such as Plaintiff Mother to utilize the products safely and with adequate protection
19 during pregnancy, or to decide to not use or ingest the APAP Products at all.

20 67. This alleged failure to warn is not limited to the information contained on the
21 APAP Products' labeling. Defendant was able, in accord with federal law, to comply with
22 relevant state law by disclosing the known risks associated with exposure to or use of APAP
23 during pregnancy through other non-labeling mediums, including, but not limited to, promotion,
24 advertisements, public service announcements, and/or public information sources. But
25 Defendant did not disclose these known risks through any medium.

26 68. At all relevant times, Defendant had a duty to properly test, develop, design,
27 manufacture, inspect, package, label, market, promote, sell, distribute, maintain, and supply the
28 APAP Products; provide proper warnings for the APAP Products; and take such steps as

1 necessary to ensure the APAP Products did not cause users and consumers, and their children,
2 to suffer from unreasonable and dangerous risks. Defendant had a continuing duty to warn
3 Plaintiff Mother of dangers associated with exposure to or use of APAP during pregnancy.
4 Defendant, as a manufacturer, seller, and/or distributor of pharmaceutical medication, is held to
5 the knowledge of an expert in the field.

6 69. At the time of manufacture, Defendant could have provided the warnings or
7 instructions regarding the full and complete risks of the APAP Products during pregnancy
8 because Defendant knew or should have known of the unreasonable risks of ASD and ADHD
9 associated with prenatal exposure to and/or the use of such products.

10 70. At all relevant times, Defendant failed and deliberately refused to investigate,
11 study, test, or promote the safety of the APAP Products, or to minimize the dangers to
12 consumers of the APAP Products and to those who would foreseeably use or be harmed by the
13 APAP Products, including Plaintiffs.

14 71. Defendant failed to adequately warn consumers, like Plaintiff Mother, about the
15 significant increased risk of neurodevelopmental disorders in children exposed to APAP
16 prenatally, including but not limited to ASD and ADHD.

17 72. Defendant failed to adequately inform reasonably foreseeable consumers, like
18 Plaintiff Mother, of the proper usage of the APAP Products.

19 73. Even though Defendant knew or should have known that APAP posed a grave
20 risk of harm to Plaintiff Child, Defendant failed to exercise reasonable care to warn of the
21 dangerous risks associated with use and prenatal exposure.

22 74. Plaintiff Mother was exposed to the APAP Products during pregnancy without
23 knowledge of their dangerous characteristics.

24 75. At all relevant times, Plaintiff Mother used and/or was exposed to the use of the
25 APAP Products while using them for their intended or reasonably foreseeable purposes during
26 pregnancy, without knowledge of their dangerous characteristics.

27 76. Plaintiff Mother could not have reasonably discovered the defects and risks
28 associated with the APAP Products prior to or at the time of Plaintiff consuming APAP during

1 pregnancy. Plaintiff Mother relied upon the skill, superior knowledge, and judgment of
2 Defendant to know about and disclose serious health risks associated with using the APAP
3 Products.

4 77. If Plaintiff Mother had been properly warned of the defects, dangers, and risks
5 associated with prenatal exposure to APAP, Plaintiff Mother would have utilized the APAP
6 Products safely and with adequate protection during pregnancy or would have decided to not
7 ingest the APAP Products at all. Defendant's failure to properly warn of those defects, dangers,
8 and risks associated with prenatal exposure to APAP was a substantial factor in causing
9 Plaintiffs' injuries and damages.

10 78. Defendant is liable to Plaintiffs for injuries caused by Defendant's negligent or
11 willful failure, as described above, to provide adequate warnings or other relevant information
12 and data regarding the appropriate use of the APAP Products and the risks associated with the
13 use of APAP.

14 79. As a direct and proximate result of Defendant placing defective APAP Products
15 into the stream of commerce, and Plaintiff Mother's foreseeable use and ingestion of the APAP
16 Products during pregnancy, Plaintiff Child was exposed to APAP prenatally, causing her to
17 develop ASD and ADHD.

18 80. As a direct and proximate result of Defendant placing defective APAP Products
19 into the stream of commerce, Plaintiffs have suffered permanent injuries, significant pain and
20 suffering, emotional distress, lost wages and earning capacity, and diminished quality of life.
21 Plaintiffs respectfully seek all damages to which they may be legally entitled.

22 **COUNT II: NEGLIGENCE**

23 81. Plaintiffs restate, reallege, and incorporate by reference each of the allegations
24 set forth in the rest of this Complaint as if fully set forth herein.

25 82. Although Defendant had a duty to use reasonable care in testing, developing,
26 designing, manufacturing, marketing, labeling, selling, distributing, promoting, and preparing
27 written instructions and warnings for the APAP Products, Defendant failed to do so.

28 83. Defendant, directly or indirectly, caused the APAP Products to be sold,

distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff Mother. At all relevant times, Defendant registered, researched, manufactured, distributed, marketed, promoted, and sold the APAP Products within this district and aimed at a consumer market within this district.

84. Defendant knew, or in the exercise of reasonable care should have known, that the APAP Products were defectively and unreasonably designed and/or manufactured, and/or marketed, and were unreasonably dangerous and likely to injure persons that were prenatally exposed to them. Defendant knew or should have known that Plaintiff Mother was unaware of the dangers and defects inherent in the APAP Products when she was ingesting them during her pregnancy with Plaintiff Child.

85. At all relevant times, Defendant had a duty to exercise reasonable care in the marketing, advertisement, promotion, and sale of the APAP Products. Defendant's duty of care owed to consumers and the general public included providing accurate, true, and correct information concerning the risks of using APAP during pregnancy and appropriate, complete, and accurate warnings concerning the potential adverse effects of APAP and, in particular, the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP.

86. At all relevant times, Defendant knew or, in the exercise of reasonable care, should have known of the hazards and dangers of APAP ingestion while pregnant and, specifically, the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP.

87. Defendant failed to provide any kind of warning to pregnant consumers, like Plaintiff Mother, about the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP.

88. Accordingly, at all relevant times, Defendant knew or, in the exercise of reasonable care, should have known that use of the APAP Products during pregnancy could cause Plaintiffs' injuries, and thus, create a dangerous and unreasonable risk of injury to the users of these products, including Plaintiffs.

89. As such, Defendant breached its duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, testing, marketing, labeling, supply, promotion, advertisement, packaging, sale, and distribution of the APAP Products, in that Defendant manufactured and produced defective APAP Products, which carry the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP; knew or had reason to know of the defects inherent in the APAP Products; knew or had reason to know that a user's or consumer's use of the APAP Products during pregnancy created a significant risk of harm and unreasonably dangerous side effects; and failed to prevent or adequately warn of these risks and injuries.

90. Defendant had a duty to disclose the truth about the risks associated with exposure to or use of APAP during pregnancy in its promotional efforts outside of the context of labeling. Defendant was negligent in its promotion of APAP outside of the labeling context by failing to disclose material risk information as part of its promotion and marketing of the APAP Products, including through the internet, television, and print advertisements.

91. Despite Defendant's ability and means to investigate, study, and test the APAP Products and to provide adequate warnings regarding use during pregnancy, Defendant failed to do so. Indeed, Defendant wrongfully concealed information and further made false and/or misleading statements concerning the safety and use of APAP.

92. Defendant's negligence included:

- a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing the APAP Products while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and studies of APAP and the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP, and, consequently, the risk of serious harm associated with human use of APAP during pregnancy;
- b. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not the APAP Products were safe for its intended

- 1 consumer use and unborn children; and
- 2 c. Failing to provide adequate instructions, guidelines, and safety
- 3 precautions to those persons Defendant could reasonably foresee would
- 4 use the APAP Products during pregnancy; and
- 5 d. Failing to disclose to Plaintiff Mother, users, consumers, and the
- 6 general public that use of APAP during pregnancy presents severe risks
- 7 of neurodevelopmental disorders in children exposed to APAP
- 8 prenatally; and
- 9 e. Failing to warn Plaintiff Mother, users, consumers, and the general
- 10 public that the APAP Products' risk of harm was unreasonable and that
- 11 there were safer and effective alternative medications or treatments
- 12 available to Plaintiff Mother and other users and/or consumers; and
- 13 f. Representing that the APAP Products were safe for their intended
- 14 purposes for pregnant women when, in fact, Defendant knew or should
- 15 have known the APAP Products were not safe for their intended
- 16 purposes; and
- 17 g. Declining to make or propose any changes to the APAP Products'
- 18 labeling or other promotional materials that would alert users,
- 19 consumers, and the general public of the risks of APAP, including to
- 20 pregnant women; and
- 21 h. Advertising, marketing, and recommending the use of the APAP
- 22 Products during pregnancy, while concealing and failing to disclose or
- 23 warn of the dangers known by Defendant to be caused by the use of or
- 24 exposure to APAP; and
- 25 i. Continuing to disseminate information to its consumers and the general
- 26 public, which indicates or implies that the APAP Products are not
- 27 unsafe for pregnant consumer use; and
- 28

1 j. Continuing the manufacture and sale of the APAP Products with the
2 knowledge that the APAP Products were unreasonably unsafe and
3 dangerous.

4 93. Defendant knew and/or should have known that it was foreseeable that children
5 such as Plaintiff Child would suffer injuries as a result of Defendant's failure to exercise
6 ordinary care in the manufacturing, marketing, labeling, distribution, and sale of the APAP
7 Products to pregnant consumers, like Plaintiff Mother.

8 94. Plaintiff Mother did not know the nature and extent of the injuries that could
9 result in her child from the intended use of and/or exposure to APAP prenatally.

10 95. Defendant's negligence was a proximate cause of Plaintiffs' injuries, i.e., absent
11 Defendant's negligence, Plaintiff Child would not have developed ASD. That negligence was a
12 substantial factor in causing Plaintiffs' injuries and damages.

13 96. Defendant's conduct, as described above, was reckless. Defendant regularly
14 risked exposing Plaintiff Mother to the APAP Products while pregnant with Plaintiff Child, with
15 full knowledge of the dangers of the APAP Products and that it could cause ASD and ADHD in
16 Plaintiff Child. Defendant made conscious decisions not to redesign, re-label, warn, or inform
17 the unsuspecting public, including Plaintiff Mother. Defendant's reckless conduct therefore
18 warrants an award of punitive damages.

19 97. As a direct and proximate result of Defendant placing the defective APAP
20 Products into the stream of commerce, Plaintiffs have suffered permanent injuries, significant
21 pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality
22 of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

23 **COUNT III: BREACH OF EXPRESS WARRANTY**

24 98. Plaintiffs restate, reallege, and incorporate by reference each of the allegations
25 set forth in the rest of this Complaint as if fully set forth herein.

26 99. At all material times, Defendant manufactured, marketed, sold, distributed, and
27 otherwise placed into the stream of commerce the APAP Products. These actions were under
28 the ultimate control and supervision of Defendant.

1 100. In advertising, marketing, and promoting the APAP Products to consumers, like
2 Plaintiff Mother, Defendant expressly warranted that the APAP Products were safe for use and
3 reasonably fit for their intended purposes, including use by pregnant mothers. In advertising,
4 marketing, and otherwise promoting the APAP Products, Defendant intended for pregnant
5 consumers to rely upon its representations regarding safety and fitness, in an effort to induce
6 them to purchase and consume the APAP Products during pregnancy to relieve pain.

7 101. Defendant expressly warranted to Plaintiff Mother and pregnant consumers that
8 the APAP Products were safe for ingestion during pregnancy.

9 102. Defendant had a duty to exercise reasonable care in the research, development,
10 design, testing, packaging, manufacture, inspection, labeling, distributing, marketing,
11 promotion, sale, and release of the APAP Products, including a duty to:

- 12 a. ensure that the APAP Products during pregnancy did not cause users and
13 their unborn children unreasonably dangerous side effects;
- 14 b. warn of dangerous and potentially incurable side effects; and
- 15 c. disclose adverse material facts, such as the true risks associated with the use
16 of and exposure to APAP during pregnancy, when making representations to
17 users, consumers, and the general public, including Plaintiff Mother.

18 103. Defendant had the ability to properly disclose the risks associated with APAP
19 usage during pregnancy through multiple channels, not just labeling.

20 104. At all relevant times, Defendant expressly represented and warranted to the
21 purchasers of the APAP Products, by and through statements made by Defendant in labels,
22 publications, brochures, and other written materials intended for consumers and the general
23 public, that the APAP Products were safe to human health and the environment, effective, fit,
24 and proper for their intended use during pregnancy. Defendant advertised, labeled, marketed,
25 and promoted the APAP Products, representing the quality to consumers and the public in such
26 a way as to induce their purchases or use during pregnancy, thereby making an express warranty
27 that the APAP Products would conform to the representations.

28 105. The representations about the APAP Products, as set forth herein, contained or

1 constituted affirmations of fact or promises made by the seller to the buyer, which related to the
2 goods and became part of the basis of the bargain, creating an express warranty that the goods
3 would conform to the representations.

4 106. Defendant breached express representations and warranties made to Plaintiff
5 Mother, with respect to the APAP Products, including the following:

- 6 a. Defendant represented through its labeling, advertising, and marketing
7 materials that the APAP Products were safe for use during pregnancy,
8 and intentionally withheld and concealed information about the risks
9 of serious injury associated with use of APAP and by expressly
10 limiting the risks associated with use during pregnancy within its
11 warnings and labels; and
- 12 b. Defendant represented that the APAP Products were safe for use and
13 intentionally concealed information that demonstrated that APAP
14 carries the significantly increased risk of causing neurodevelopmental
15 disorders in children through prenatal exposure to APAP, and that the
16 APAP Products, therefore, were not safer than alternatives available
17 on the market.

18 107. Plaintiff Mother detrimentally relied on the express warranties and
19 representations of Defendant concerning the safety and/or risk profile of APAP during
20 pregnancy in deciding to purchase the APAP Products. Plaintiff Mother reasonably relied upon
21 Defendant to disclose known defects, risks, dangers, and side effects of APAP. Plaintiff Mother
22 would not have purchased or used the APAP Products during pregnancy had Defendant
23 properly disclosed the risks associated with the APAP Products, either through advertising,
24 labeling, or any other form of disclosure. Defendant's breach of the express warranties and
25 representations concerning the safety and/or risk profile of APAP during pregnancy was a
26 substantial factor in causing Plaintiffs' injuries and damages.

1 108. Plaintiff Mother had no knowledge of the falsity or incompleteness of
2 Defendant's statements and representations concerning the APAP Products and could not have
3 taken reasonable steps to notify Defendant of those matters or to seek repair or other remedies.

4 109. Plaintiff Mother used and/or was exposed to APAP during pregnancy as
5 researched, developed, designed, tested, manufactured, inspected, labeled, distributed,
6 packaged, marketed, promoted, sold, or otherwise released into the stream of commerce by
7 Defendant.

8 110. Had the warnings, labels, advertisements, or promotional material for the APAP
9 Products accurately and adequately set forth the true risks associated with the use of such
10 Products during pregnancy, including Plaintiffs' injuries, rather than expressly excluding such
11 information and warranting that the APAP Products were safe for their intended use, Plaintiffs
12 could have avoided the injuries complained of herein.

13 111. As a direct and proximate result of Defendant's breach of express warranty,
14 Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress,
15 lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all
16 damages to which they may be legally entitled.

17 **COUNT IV: BREACH OF IMPLIED WARRANTY**

18 112. Plaintiffs restate, reallege, and incorporate by reference each of the allegations
19 set forth in the rest of this Complaint as if fully set forth herein.

20 113. At all material times, Defendant manufactured, marketed, sold, distributed, and
21 otherwise placed the APAP Products into the stream of commerce.

22 114. At all material times, Defendant intended for the APAP Products to be consumed
23 and ingested by pregnant women, like Plaintiff Mother; and Defendant impliedly warranted that
24 the APAP Products and their component parts were of merchantable quality, safe, fit for such
25 use, and adequately tested.

26 115. Defendant was aware that consumers, including Plaintiff Mother, would
27 consume and ingest the APAP Products as directed by the Products' labels and promotional
28 materials. Therefore, Plaintiff Mother was a foreseeable user of the APAP Products.

116. But Defendant failed to disclose that APAP has dangerous propensities when used as intended during pregnancy and that use of the APAP Products carries an increased risk of developing severe injuries, including Plaintiff Child's injuries.

117. The APAP Products were expected to reach, and did in fact reach consumers, including Plaintiff Mother, without substantial change in the condition in which they were manufactured and sold by Defendant.

118. Plaintiff Mother was an intended beneficiary of the implied warranties made by Defendant to purchasers of the APAP Products, including Plaintiff Mother.

119. In reliance upon Defendant's implied warranties, Plaintiff Mother purchased and used the APAP Products as indicated, and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendant. The failure of the APAP Products to be of merchantable quality, to be safe or fit for their intended use, or to be adequately tested was a substantial factor in causing Plaintiffs' injuries and damages.

120. Defendant breached its implied warranties to Plaintiffs in that the APAP Products were not of merchantable quality, nor were they safe or fit for their intended use or adequately tested.

121. The harm caused by the APAP Products far outweighed their benefit, rendering the APAP Products more dangerous than an ordinary consumer or user would expect and more dangerous than alternative products.

122. As a direct and proximate result of Defendant's breach of express warranty, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

COUNT V: VIOLATION OF CONSUMER PROTECTION LAWS

123. Plaintiffs restate, reallege, and incorporate by reference each of the allegations set forth in the rest of this Complaint as if fully set forth herein.

124. Plaintiff Mother purchased and used the APAP Products for primarily personal use and pain relief during pregnancy, thereby suffering ascertainable losses as a result of

1 Defendant's actions in violation of the consumer protection laws.

2 125. Had Defendant not engaged in the deceptive conduct described in this
3 Complaint, Plaintiff would not have purchased and/or paid for the APAP Products, and
4 Plaintiffs would not have incurred related injury medical costs.

5 126. Defendant engaged in wrongful conduct and unlawful while at the same time
6 obtaining under false pretenses moneys from Plaintiff for the APAP Products. Those moneys
7 would not have been paid had Defendant not engaged in unfair and deceptive conduct. Plaintiffs
8 actually relied upon Defendant's misrepresentations and deception concerning the APAP
9 Products.

10 127. Defendant engaged in the following unfair methods of competition or deceptive
11 acts or practices, which are proscribed by law:

- 12 A. representing that goods or services have characteristics,
13 ingredients, uses, benefits, or qualities they do not have; and
- 14 B. advertising goods or services with the intent not to sell them as
15 advertised; and
- 16 C. engaging in fraudulent or deceptive conduct creating a likelihood
17 of confusion or misunderstanding.

18 128. Plaintiffs were injured by the cumulative nature of Defendant's conduct. The
19 cumulative effect, directed at patients, physicians, and consumers, was to create demand for and
20 sell the APAP Products. Each aspect of Defendant's conduct combined to artificially create
21 sales of the APAP Products, including to Plaintiff Mother who did, in fact, purchase the APAP
22 Products.

23 129. Defendant had a statutory duty to refrain from unfair or deceptive acts or trade
24 practices in the design, labeling, development, manufacture, promotion, and sale of the APAP
25 Products.

26 130. Defendant's deceptive, unconscionable, or fraudulent representations and
27 material omissions to consumers, including Plaintiff Mother, constitute unfair and deceptive
28 acts and trade practices in violation of the federal and state consumer protection statutes listed

below.

131. Defendant's actions, as complained of in this Complaint, constitute unfair competition or unfair, unconscionable, deceptive, or fraudulent acts or trade practices in violation of the federal and state consumer protection statutes listed below.

132. Defendant has engaged in unfair competition, or unfair or deceptive acts or trade practices, or has made false representations under the following statutes:

- 15 U.S.C. §§ 2301–12 (1982);
- Cal. Bus. & Prof. Code § 17200, et seq.;
- Cal. Civ. Code § 1750 et seq.

133. To protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices, and false advertising, Defendant, as the supplier, manufacturer, advertiser, and seller, is subject to liability under the above legislation enacted against unfair, deceptive, fraudulent, and unconscionable consumer sales practices. The California Unfair Competition Law ("UCL") prohibits "any unlawful, unfair, or fraudulent business act or practice and unfair, deceptive, untrue, or misleading advertising and any act prohibited by" Section 17500 of the California Business and Professions Code. Section 17500, in turn, prohibits any untrue or misleading statements made in connection with the sale of goods. The Consumers Legal Remedies Act ("CLRA") defines as statutorily unlawful certain unfair methods of competition and unfair or deceptive practices. Cal. Civ. Code § 1750 et seq.

134. By knowingly and falsely representing that the APAP Products were fit to be used for the purposes for which they were intended—when in fact they were defective and dangerous when used during pregnancy—and by other acts alleged, Defendant violated the above statutes, enacted to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices, and false advertising.

135. Defendant's actions and omissions are uncured or incurable, deceptive acts under the above legislation.

136. Defendant had actual knowledge of the defective and dangerous conditions of the APAP products but failed to take any action to cure such defective and dangerous

1 conditions.

2 137. Plaintiff Mother relied upon Defendant's misrepresentations and omissions in
3 determining which APAP Products (if any) to ingest.

4 138. Defendant's deceptive, unconscionable, or fraudulent representations and
5 material omissions to consumers constituted unfair and deceptive acts and practices.

6 139. By reason of the unlawful acts in which Defendant engaged, and as a direct and
7 proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

8 140. As a direct and proximate result of Defendant's violations of the above-listed
9 legislation, Plaintiffs have sustained economic losses and other damages and are entitled to
10 statutory and compensatory damages, including restitution, in an amount to be proven at trial
11 and civil penalties as permitted by law.

12 **COUNT VI: NEGLIGENT MISREPRESENTATION**

13 141. Plaintiffs restate, reallege, and incorporate by reference each of the allegations
14 set forth in the rest of this Complaint as if fully set forth herein.

15 142. Defendant had a duty to accurately and truthfully represent to consumers,
16 including to Plaintiff Mother and to the public, that the APAP Products had not been adequately
17 tested and found to be a safe and effective treatment for pregnant women. Defendant breached
18 that duty as its representations of the safety of the APAP Products were false. Defendant
19 intended for consumers like Plaintiff Mother to rely upon that representation, Plaintiff Mother
20 did justifiably rely on Defendant's misrepresentations concerning the APAP Products' high risk
21 of unreasonable and dangerous adverse side effects when ingested or used during pregnancy.

22 143. Defendant failed to exercise ordinary care in the representations concerning the
23 APAP Products while Defendant was involved in its manufacture, sale, testing, quality
24 assurance, quality control, and distribution in interstate commerce, because Defendant
25 negligently misrepresented the APAP Products' high risk of unreasonable and dangerous
26 adverse side effects when ingested or used during pregnancy.

27 144. Defendant also breached its duty in representing to Plaintiff Mother that the
28 APAP Products had no serious side effects when ingested during pregnancy. Defendant

1 intended for consumers like Plaintiff Mother to rely upon that representation, and Plaintiff
2 Mother did justifiably rely upon that representation.

3 145. Defendant knew or had reason to know that the APAP Products had been
4 insufficiently tested or had not been tested at all; and that they lacked adequate and accurate
5 warnings, and created a high risk, or a higher than acceptable reported and represented risk, of
6 adverse side effects. Those side effects include neurodevelopmental disorders in children, such
7 as ASD and ADHD. Thus, Defendant lacked reasonable ground for believing the
8 representations to be true and intended for consumers like Plaintiff to rely upon those
9 misrepresentations by purchasing the APAP products for use during pregnancy. Plaintiff
10 Mother justifiably relied upon those misrepresentations in purchasing and using the APAP
11 products while pregnant. Defendant's negligent misrepresentations concerning the safety
12 and/or risk profile of using APAP during pregnancy was a substantial factor in causing
13 Plaintiffs' injuries and damages.

14 146. As a direct and proximate result of Defendant's negligent misrepresentation,
15 Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress,
16 lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all
17 damages to which they may be legally entitled.

18 **PUNITIVE DAMAGES**

19 147. Plaintiffs restate, reallege, and incorporate by reference each of the allegations
20 set forth in the rest of this Complaint as if fully set forth herein.

21 148. Defendant has acted with malice through despicable conduct that exhibits a
22 willful and conscious disregard for the rights and safety of others, including Plaintiffs, and has
23 acted with oppression in subjecting Plaintiffs to cruel and unjust hardship in conscious disregard
24 of their rights. Further, Defendant has intentionally misrepresented or concealed material facts
25 known to it with the intention of causing injury or otherwise depriving Plaintiffs of their
26 property or legal rights.

27 149. Defendant failed to adequately test and study the APAP Products to determine
28 and ensure that the APAP Products were safe and effective for use during pregnancy before

1 releasing them for sale for human consumption.

2 150. Further, Defendant continued to manufacture and sell the APAP Products and
3 marketed them for use during pregnancy, even after obtaining knowledge and information that
4 the APAP Products were defective and unreasonably unsafe because they, among other things,
5 did not include adequate warnings.

6 151. Defendant was aware of the probable consequences of the dangerous and
7 defective product, including the risk of neurodevelopmental disorders in children, such as ASD
8 and ADHD, when they suffered prenatal exposure.

9 152. At all material times, Defendant knew or should have known that the APAP
10 Products were inherently dangerous with respect to the following: the risk of
11 neurodevelopmental disorders in children, such as ASD and ADHD, when they suffered
12 prenatal exposure; pain and suffering; loss of life's enjoyment; and unsuccessful treatments to
13 cure the conditions proximately related to the use of the APAP Products, as well as the other
14 permanent and lasting severe personal injuries.

15 153. Defendant knowingly withheld material information from consumers and the
16 public, including Plaintiff Mother, concerning the safety and efficacy of the APAP Products
17 during pregnancy, which deprived Plaintiff Mother of vitally necessary information with which
18 to make a fully informed decision about whether to use the APAP Products while pregnant.

19 154. At all material times, Defendant also knew and recklessly and/or intentionally
20 disregarded the fact that the APAP Products, when used during pregnancy, can cause
21 debilitating and life-altering side effects with greater frequency than safer alternative methods,
22 products, and/or treatments. But Defendant recklessly failed to advise the medical community
23 and the general public, including Plaintiff Mother, of that fact.

24 155. At all material times, Defendant intentionally misstated and misrepresented data;
25 and Defendant continues to misrepresent data so as to minimize the perceived risk of injuries
26 and the rate of complications caused by or associated with the APAP Products.

27 156. Notwithstanding the foregoing and the growing body of knowledge and
28 information regarding the true and defective nature of the APAP Products, with their increased

1 risk of side effects and serious complications, Defendant continues to aggressively market the
2 APAP Products to consumers, including the pregnant community at large, without disclosing
3 the true risk of the complications and side effects.

4 157. When Plaintiff Mother consumed the APAP Products and since then, Defendant
5 has known the APAP Products were defective and unreasonably dangerous without an adequate
6 warning. But Defendant continued to manufacture, produce, assemble, market, distribute, and
7 sell the APAP Products to the pregnant community so as to maximize sales and profits at the
8 expense of the health and safety of expecting mothers in a conscious, reckless, and/or
9 intentional disregard of the likely and foreseeable harm caused by the APAP Products to
10 members of the public, including Plaintiffs.

11 158. At all material times, Defendant has concealed and/or failed to disclose to the
12 public the serious risks and the potential complications associated with the APAP Products, so
13 as to ensure continued and increased sales and profits and to the detriment of the public,
14 including Plaintiffs.

15 159. Defendant's acts and omissions are of such character and nature so as to entitle
16 Plaintiffs to an award of punitive damages in accordance with applicable statutory and common
17 law. Defendant's conduct shows malice, oppression, or fraud, or that entire want of care,
18 raising the presumption of conscious indifference to consequences of that conduct, thereby
19 justifying an award of punitive damages.

20 WHEREFORE, Plaintiffs demand judgment against Defendant individually, and jointly
21 and severally. Plaintiffs also request compensatory damages, punitive damages, or enhanced
22 compensatory damages, together with interest, costs of suit, attorneys' fees, and such further
23 relief as the Court deems equitable and just.

24 **PRAYER FOR RELIEF**

25 Plaintiffs demand judgment against Defendant, individually, and jointly and severally,
26 and prays for the following relief in accordance with applicable law and equity:

- 27 i. Compensatory damages to Plaintiffs for past, present, and future damages,
28 including pain and suffering for severe and permanent personal injuries

- 1 sustained by Plaintiffs, permanent impairment, mental pain and suffering,
2 loss of enjoyment of life, health and medical care costs, economic
3 damages, together with interest and costs as provided by law; and
4 ii. Restitution and disgorgement of Defendant's profits; and
5 iii. Applicable statutory penalties; and
6 iv. Punitive or enhanced damages; and
7 v. Reasonable attorneys' fees as provided by law; and
8 vi. Past and future costs of all proceedings; and
9 vii. All ascertainable economic damages; and
10 viii. Prejudgment interest on all damages as allowed by law; and
11 ix. Such other and further relief as this Court deems just and proper.

12 **DEMAND FOR JURY TRIAL**

13 Plaintiffs hereby demands a trial by jury on all issues so triable.

14 Dated: October 3, 2022

Respectfully submitted,

15 

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